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SURGICAL CLIP

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Inventor:	GIDDINS DARREN JOHN (GB); FILSHIE MARCUS (GB)	
Applicant:	GIDDINS DARREN JOHN (GB); FEMCARE LTD (GB); FILSHIE MARCUS (GB)	Cited documents: ☐ GB2177748 ☐ US5219353
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Abstract of WO0105309

Priority number(s): GB19990016484 19990715

A surgical clip comprises an upper jaw (12) and a lower jaw (14), a section lining, and includes a complex shape for the upper jaw (12) comprising a first generally straight section (120) and a second shallow curved section (122) thereby enabling the clip to be inserted down a narrow magazine tube and to be able to be operable into a wide capture opening to capture larger vessels and then closed into a latched position on application of force the relatively straight section (120) and then to the shallow curved section (122).

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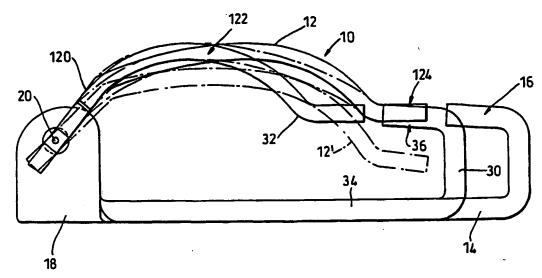
- (74) Agent: BAKER, Colin, J.; Eric Potter Clarkson, Park View House, 58 The Ropewalk, Nottingham NG1 5DD (GB).
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(54) Title: SURGICAL CLIP



(57) Abstract: A surgical clip comprises an upper jaw (12) and a lower jaw (14), a section lining, and includes a complex shape for the upper jaw (12) c mprising a first generally straight section (120) and a second shallow curved section (122) thereby enabling the clip to be inserted down a narrow magazine tube and to be able to be operable into a wide capture opening to capture larger vessels and then closed into a latched positi n on applicati n of force the relatively straight section (120) and then to the shallow curved section (122).

11/05309 A1

SURGICAL CLIP

The present invention relates to surgical clips and more particularly to ligation clips.

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During surgical procedures, it is often necessary to use several ligation clips. These can be inserted individually into a suitable applicator, but is more efficient if several clips can be loaded into an applicator preferably in a replaceable magazine.

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The present invention has for a first object to provide a clip in particular suitable as a ligation clip which can be loaded into a relatively narrow diameter magazine for delivering such clips down a tube which may be inserted down a cannula.

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During surgical procedures, ligation clips can be extensively used; several may be applied to various anatomical structures in the course of one operation.

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State of the art clips are limited to the use on anatomical structures up to 5mm in diameter after which their effectiveness becomes impaired.

It is the object of this invention to provide a ligation clip that can be used on anatomical structures up to and in excess of 5mm in diameter.

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In particular, the object of the invention is to provide a surgical clip that can be loaded into a dedicated applicator (incorporating a magazine) for delivery down a narrow cannula.

The increased effectiveness in dealing with larger structures will mean that the simpler clipping technique can be used instead of ligature sutures that require a longer training curve and take longer to apply thus simplifying the equipment required.

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In addition the increased effectiveness of clipping means that only the smallest number of clips required needs to be used; this will reduce the degree of intervention necessary.

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The dedicated applicator is designed in relation to the clip and is disclosed

in co-pending application No....

The clip is designed to be able to be loaded into the magazine of the applicator shaft (in multiples of two to ten). The applicator shaft or barrel

incorporating different multiples of clips may be disposable.

The geometry of the upper jaw of the clip is critical when having to occlude anatomical structures greater than 5mm in diameter. The upper jaw must be able to withstand deformation whilst occluding a structure until the upper jaw is safely within the confines of the latch (opposite end

to the hinge).

In addition the geometry of the upper jaw also allows for the increased capacity for occlusion that is necessary when occluding larger structures.

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If the cannula can be made to a large diameter then the design of the clip can be relatively simple but as the diameter of the cannula is reduced then the clip design must be more complex in order to be able to provide an elongate magazine to enable the clips firstly to be fed down the cannula, secondly to be able to be openable once it has emerged from the magazine

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and thirdly to be able to be lockable by the applicator to effect closure of a blood vessel. A mere enlargement of existing clip design may not achieve a satisfactory locking procedure for the enlarged clip.

It is an object of the present invention to provide a surgical clip which can 5 occlude larger structures and also which can preferably be inserted into a narrow applicator for subsequent insertion down a narrow cannula.

In a specific example the cannula can be less than 7mm in diameter and in a preferred example it can be less than 5mm in diameter. 10

The present invention provides a surgical clip, the clip comprising an elongate upper jaw and an elongate lower jaw attached together at a first hinge end, the lower jaw being provided with latching means at an opposite end to the hinge, the jaws being provided with a silicone rubber lining on either the upper or lower jaw, or both, and in which the upper jaw comprises a complex shape comprising a first substantially straight section adjacent to the hinge and a second arcuate shaped section adjoining the straight section.

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In a preferred embodiment, the arcuate section comprises a third generally straight section adjacent to said curved section at the opposite end of the upper jaw to the large section said substantially straight section, when in the closed position of the clip interlocking under the latching section of the lower jaw.

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Embodiments of the present invention will now be described, by way of example with reference to the accompanying drawings in which:

Figure 1 shows an enlarged side elevation view of a first clip in accordance with the present invention, the figure also showing by way of comparison a side elevation view of a known sterilisation clip;

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Figure 2 shows diagrammatically a longitudinal cross-section of a part of an applicator illustrating the portion of the clip of the present invention in a magazine section of the application and also in the operable position in which position the clip is closed, as illustrated,

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Figures 3 to 5 diagrammatically illustrate the advantageous design of the clip of the present invention during closure,

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Figure 6 shows an enlarged side elevation view of a second clip in accordance with the present invention,

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Figure 7 shows a cross sectional view on line 'A-A' of Figure 6 illustrating the cross sectional shape of the silicone rubber lining of the upper jaw of the clip,

Figure 8 shows a cross sectional view on line 'B-B' of Figure 6 illustrating the cross sectional shape of the silicone rubber lining of the lower jaw of the clip,

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Figure 9 shows a detail of the end, closure section of the upper jaw of the clip of Figure 6 and

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Figure 10 shows the upper jaw of the clip of figure 6 in greater detail.

With reference to Figure 1, a clip 10 according to the present invention is shown in side elevation.

The clip comprises an upper jaw section 12 and a lower jaw section 14.

The lower jaw section 14 has a latch portion 16 at one end a hinge portion 18 at the other end.

The upper jaw 12 is hinged by a hinge pin 20 to the lower jaw.

10

The upper jaw 12 comprises at least two shaped sections. A first section 120 comprises a relatively straight short section and the second section 122 comprises a relatively gently curved section.

15 A third section 124 comprising a co-operating latch portion may be provided at the end of the upper jaw opposite to the hinge 18.

In a practical clip (see Figure 2) one or both jaws 12, 14 will be provided with a silicone rubber lining but this is not shown in Figure 1 for ease of viewing.

The jaw 12 is shown in a second position 12' to illustrate movement of the jaw which is further illustrated in Figure 2.

25 By way of contrast, a known sterilisation clip 30 (the Filshie clip) is shown in Figure 1 having a bottom jaw 34 and top jaw 32 and using the same hinge 18. The latch portion 36 can be seen to be substantially nearer to the hinge 18 than the latch portion 16 of the clip according to the present invention.

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The top jaw 32 is as shown a substantially constant curve.

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The advantage of the clip design according to the present invention is that the straight section and shallow curve allows the clip (see Figure 2) to pass down (or be fed down) a relatively narrow diameter (H) tube and also to then open to provide an opening (capture) width W which is substantially greater than the height H even with the presence of the silicone rubber lining 40.

- The straight section 120 in combination with the shallow curve section operates in a manner which is particularly advantageous with a slightly longer clip. The original Filshie clip provides an overall clip length of approximately 14mm but the new clip can be 16mm or greater.
- 15 If the original clip design were to be made longer then the upper jaw would be a longer arcuate curve. When pressure is applied to this curve, the upper jaw will deform but the combination of longer jaw and the silicone lining may cause the upper jaw end section 124 to either completely fail to enter under the latch section 16 (Fig 4) or possibly to meet against the end position 160 (Fig 3) and not slide under the latch.

In the first case, the surgeon will be aware that the clip has failed but in the second case Fig 3 the surgeon may assume that correct closure has occurred but the clip will fail at a later stage due to the pressure exerted by the silicone rubber lining after the operation has been completed.

With the present design of the upper jaw, with the initial straight section it can be seen in Figure 5 that the jaw when distorted by the applicator fits within the latch because the initial closing pressure is on the straight section and thus the initial pressure does not distort the curved section

until the end portion 124 (Fig 1) has been depressed towards the lower jaw 14.

Figure 6 shows an alternative design clip 60 comprising a lower jaw 622 and an upper jaw 642. As in Figure 1 the lower jaw comprises a hinge portion 620 an elongate relatively straight portion 622 and a latch portion 624.

The upper jaw 642 comprises four separate straight and arcuate sections.

A first substantially straight portion 640, a second arcuate portion 642 having a radius RX (Figure 10) and a third arcuate portion 646 having a radius RY (Figure 10) and a fourth substantially straight section 646.

At the distal end from hinge section 620 the portion 646 is provided to latch under lip 626.

The clip 60 is preferably lined with silicone rubber linings 628 and 648 respectively attached to the lower and upper jaws 622, 642.

20 The profiles of the linings 628, 648 are shown respectively in Figures 7 and 8 and comprise a sinusoidal shape on the internal surface. This shape provides the desired property of the silicone rubber lining of being able to grip the vessel to be occluded whilst still being able to exert the necessary occlusion force when the clip has been closed.

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With reference now to Figure 9 the end section 646 (Fig 6) of the upper jaw comprises a relatively short straight section and the silicone rubber lining is provided with a tongue 6480 which is relatively thin in comparison with the rest of the lining 648.

The tongue 6480 serves to initially capture the vessel to be occluded providing in effect an extension to the upper jaw. Because the tongue 6480 is relatively thin it is readily squashed into the silicone rubber lining 628 of the lower jaw thereby not preventing closure of the clip.

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With reference now to figure 10 in order to effect satisfactory closure of the clip whilst allowing the clip to pass down a relatively small diameter tube the upper jaw of the clip is provided with a first substantially straight portion 640 at the proximal end nearest the hinge as in the embodiment of Figure 1.

In this embodiment the upper jaw is then provided with two arcuate sections 642 and 644.

15 /

Arcuate section 642 has a radius of curvature RX much larger than that of section 644 (R2). In a specific embodiment the radius of arcuate of RX is 11.9mm and that of RY is 4.6mm.

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The use of two different radii in combination with the straight section allows the clip in this embodiment to be fed down a small diameter tube in a semi closed position to be openable at the end of the tube and to then be latched without risk of the upper jaw being distorted when the latching pressure is applied.

CLAIMS

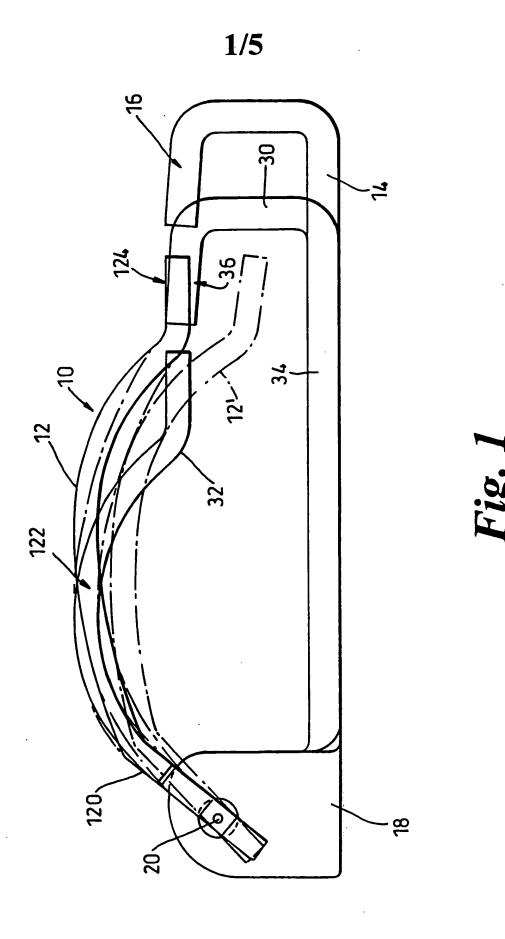
1. A surgical clip, the clip comprising an elongate upper jaw and an elongate lower jaw attached together at a first hinge end, the lower jaw being provided with catching means at an opposite end to the hinge, the jaws being provided with a section rubber lining on either the upper or lower jaw, and in which the upper jaw comprises a complex shape comprising a first substantially straight section adjacent to the hinge and a second arcuate shaped section adjoining the straight section.

- 2. A surgical clip as claimed in Claim 1, in which the arcuate section comprises a third generally straight section adjacent to said curved section at the opposite end of the upper jaw to the large section said generally straight section, when in the closed position of the clip interlocking under the latching section of the lower jaw.
- 3. A surgical clip as claimed in claim 1 or claim 2 on which the second arcuate shaped section comprises a first portion adjacent to said substantially straight section and a second portion adjacent to said first portion at an opposite end of said first portion to said substantially straight section said first portion having a first radius of curvature substantially greater than said second portion which has a second radius of curvature.

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4. A surgical clip as claimed in claim 3 in which said first radius of curvature is of the order of three times that of the second radius of curvature.



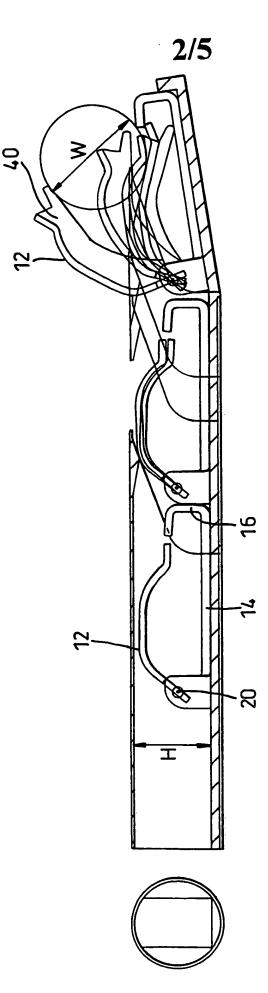
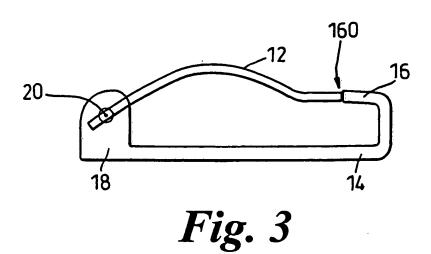
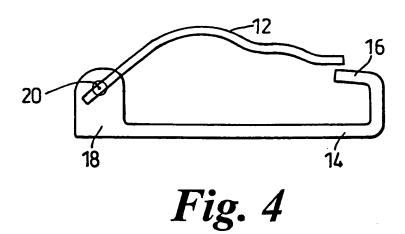
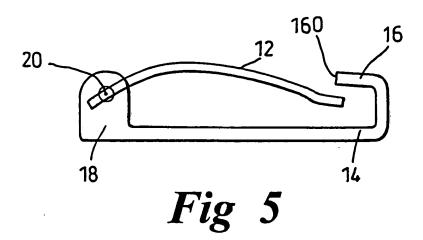


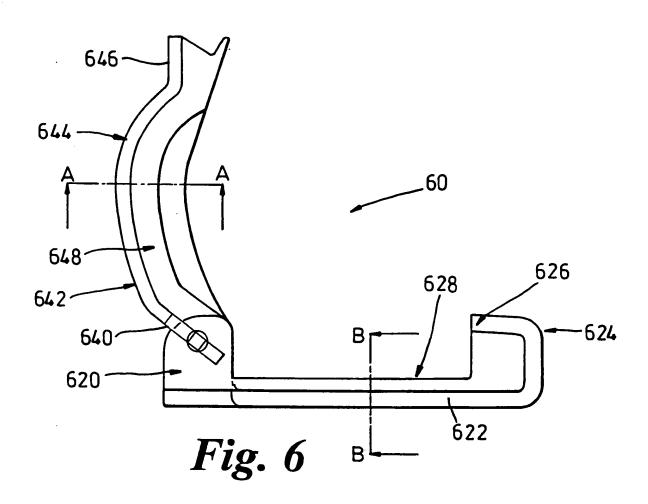
Fig. 2











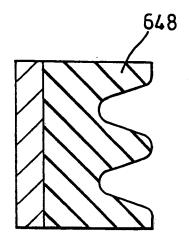


Fig 7

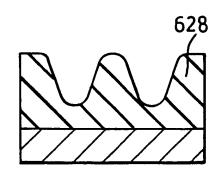
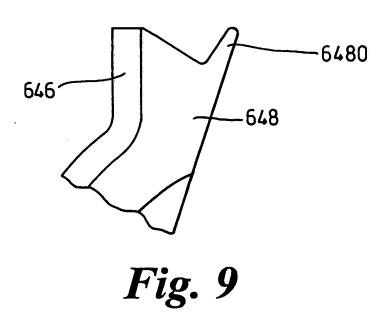
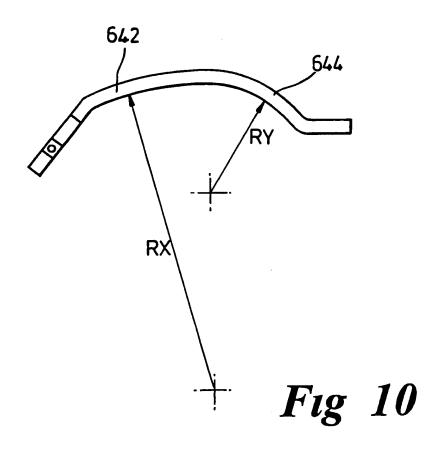


Fig. 8

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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUM	ENTS CONSIDERED TO BE RELEVANT	
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	GB 2 177 748 A (FEMCARE LIMITED) 28 January 1987 (1987-01-28) the whole document	1,2
Υ	US 5 219 353 A (GARVEY, III ET AL.) 15 June 1993 (1993-06-15) column 4, line 14-44; figures	1,2
A	GB 2 226 958 A (FEMCARE LIMITED) 18 July 1990 (1990-07-18) abstract; figures	1
Α	US 3 270 745 A (WOOD) 6 September 1966 (1966-09-06) column 4, line 46-63; figures 21-24	1
••	6 September 1966 (1966-09-06)	

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Date of the actual completion of the international search	Date of mailing of the international search report			
12 September 2000	19/09/2000			
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentiaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo ni, Fax: (+31-70) 340-3016	Authorized officer Giménez Burgos, R			

INTERNATIONAL SEARCH REPORT

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C.(Continu	Ition) DOCUMENTS CONSIDERED TO BE RELEVANT	
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	FR 2 709 944 A (CUILLERON) 24 March 1995 (1995-03-24) abstract; figures	1

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information on patent family members

PCT/GB 00/02709

Patent document cited in search report		Publication date	Patent family member(s)			Publication date
GB 2177748	A	28-01-1987	CA DE	1287538 3623023		13-08-1991 15-01-1987
			FR	2584602	A	16-01-1987
US 5219353	Α	15-06-1993	AU	3802493	Α	13-09-1993
			DE	69325089	D	01-07-1999
			DE	69325089	T	18-11-1999
			DE	627896	T	30-11-1995
			EP	0627896	A	14-12-1994
			JP	8501223	T	13-02-1996
			US	5354306	A	11-10-1994
			WO	9316645	A	02-09-1993
GB 2226958	A	18-07-1990	GB	2190297	A,B	18-11-1987
US 3270745	Α	06-09-1966	NONE			
FR 2709944	Α	24-03-1995	NONE			